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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,856	03/30/2004	Douglas A. Lappi	66785-017	5576

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,856

Applicant(s)

LAPPI ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-36 is/are pending in the application.
- 4a) Of the above claim(s) 26,29-31,33 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,27,28,32,34,35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

1. Claims 25-36 are pending.

Response to election of species requirement filed 08/21/2006 is acknowledged. Applicant elected aeruginosa exotoxin A fragment as species of toxin. Examiner apologizes for being not specific enough in the initial election of species requirement mailed on 02/08/2006. However, as the election of species required election of a single disclosed species of "polypeptide which inhibits polypeptide synthesis", rather than a subgenus, such as "a toxin", a further additional election of species requirement was deemed necessary. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Claims 26,29-31,33,36 are withdrawn from consideration as being directed to non-elected species. Claims 25,27,28,32,34,35 are under consideration.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25,27,28,32,34,35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. The rejections are applied for the following reasons of record:

A. Claim 25: The claim address "analog of Substance P". Except for two particular species of analogs of Substance P (SEQ ID Nos. 1,2), no information is provided in the specification on the meaning of the term "analog". It is not clear, whether the analogs encompassed by the claims are functional or structural; if the latter is true, what is a core structure required to constitute "an analog". The only structural characteristic claimed is the amide moiety at carboxy terminal. The claims to "analogs" encompass not only fragments but also modified analogs. Despite the presence of certain examples of substance P analogs in specification, the core structure needed for the functional characteristic of the "analogs" - binding to NK-1 receptor - is not clear and is not defined either in specification or in prior art. Accordingly, as the specification does not provide a standard for ascertaining the requisite product, one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

B. Claims 32,34: Similarly, in regard to analogs of toxins, the term "analog of a fragment of a toxin" (exotoxin, in particular) that inhibits protein synthesis is vague and indefinite. The claims are drawn to any analog [of a fragment of a toxin] that inhibits protein synthesis. The term "analog", in the case of analogs of fragment of a toxin, encompasses any modified and truncated analog of a toxin fragment, down to a single modified amino acid, that inhibits protein synthesis. The latter functional characteristic broadly encompass inhibition of synthesis of any protein, even the toxin itself. There is no teaching on core structure of a toxin analog required for such common utility, and one skilled in the art would not be appraised of the scope of the invention.

Claim Rejections - 35 USC § 102.

3. Claims 25,27,28,32,34,35 are rejected under 35 U.S.C. 102(a) as anticipated by Leeman et al. (WO 97/13410).

Leeman et al. (WO 97/13410) teaches conjugate comprising substance P (claim 3) and pseudomonas exotoxin or fragment thereof (claims 16,27). Substance P addressed in the reference is viewed as the "analog" of the elected substance P derivative of SEQ ID No. 2.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 25,27,28,32,34,35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No.6063758. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the claims of '758 are directed to conjugates comprising Substance P or analogs thereof, such as the instant SEQ ID No. 2 and a ribosome-inactivating proteins, such as pseudomonas aeruginosa toxin.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER